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EUROPEAN PATENT APPLICATION

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Disposable device for use in chemical, immunochemical and microorganism analysis.

In accordance with an embodiment of the present invention, a substantially rigid, multi-well, self-pipetting device for use in chemical, immunochemical and microorganism analysis is provided. The device includes a substantially rigid, substantially planar frame having, in operational orientation, a front face, a back face, a top edge and a bottom edge. A plurality of test wells are disposed within the device between the front face and the back face, usually in a linear array. A filling manifold is located within the device. The filling manifold is in fluid communication with each of the test wells through a filling passageway. A docking port is provided in the device which is adapted for receiving a reservoir holding a fluid specimen. The docking port is disposed on a peripheral surface of the device. The docking port is in fluid communication with the filling manifold through a filling port and a filling channel disposed within the device. With the device

in its operational orientation, the test wells, filling channel, filling manifold and filling port are located at a level lower than the surface of the fluid in the reservoir.

The device has a vent control system, also in fluid communication with the test wells, which is comprised of one or more vent manifolds, and/or valves to a vent manifold, and/or one or more vent holes or other passages to the ambient atmosphere. These vent holes, if present, are temporarily closed by a film or other means. With the device in its operational position, the vent manifold and/or vent holes of the vent control system are positioned higher than the surface of the fluid in the reservoir. The test wells are connected to the filling manifold and the vent control system according to the filling sequence. The reservoir is also connected to the vent control system through a vent port and a vent channel. The fluid specimen in the reservoir therefore

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DETAILED DESCRIPTION OF THE INVENTION

As shown in Figures 1, 2 and 3, the disposable, multi-well, self-pipetting device of the present invention consists of a frame 11 made from a solid block of acrylic plastic or other suitable material. As shown in Figure 1 a filling manifold system 13 is formed in the surface of the frame by machining of grooves or other suitable method. The filling manifold system 13 includes a filling manifold 15 and a series of filling passageways 17 leading from the filling manifold 15 to each of a series of test wells 19. As shown in Figure 2 a venting manifold system 21 is formed in a similar fashion on the back side of the frame 11. The venting manifold system 21 includes a venting manifold 23 and a series of venting passageways 25 leading from the test wells 19 to the venting manifold 23. The filling manifold system 15 and the venting manifold system 21 are machined or otherwise formed on opposite sides of the frame 11. The test wells 19 are drilled or otherwise formed through the frame. After the frame has been formed with the filling manifold system 13 on one side and the venting manifold system 15 on the other side and the test wells 19 have been drilled therein, the cartridge is completed by gluing or otherwise securing a flexible or rigid sheet 26 of transparent plastic or other suitable material onto the front side and back side of the frame.

A docking port 27 is formed on a peripheral surface, which can be an edge or planer surface, of the frame 11. The docking port 27 is adapted to receive a specimen reservoir or vial 29. As shown in Figures 1 and 2 the docking port 27 comprises a screw type cap which is affixed to the periphery of the frame 11. The screw cap receives the threads of a specimen vial 29 when it is desired to use the cartridge of the invention. A filling channel 31 is drilled or otherwise formed through the frame 11 and leads from a filling port 32 to form a fluid communication channel with the filling manifold system 13. A venting channel 33 is also drilled or otherwise formed through the frame 11 and leads from a venting port 34 to form a fluid communication channel with the venting manifold system 23.

In use, a reservoir 29, such as a vial, containing a sample of inoculated serum or other fluid specimen is screwed into a mating relationship with the docking port 27. The device is oriented in a vertical position and is placed in a rack for incubation of the inoculum. The test wells 19 are provided with a variety of dry chemicals such as freeze dried carbohydrate media, prior to sealing the test wells, which react with various microorganisms or other analytes of interest. A color change in a series of test wells indicates the reactants which react with the microorganism to provide

identification of the microorganism.

Gravity is used to move the fluid specimen with no need for a pressure or vacuum source. The junction of the venting passageways 25 with the venting manifold 23 of the venting system 21 is always at an elevation higher than the surface of the fluid in the reservoir 29 when the device is located in its operational position. Usually, the entire venting manifold is at an elevation higher than the surface of the fluid, although sections of the venting manifold 23 between the junction of the venting passageways 25 and the venting manifold could be lower than the surface of the fluid. As shown in Figures 1, 2, 3, 4 and 5 the venting port 34 of the venting manifold system 21 is also positioned higher than the surface level of the liquid specimen in the vial when the device is inverted into operating position. For other embodiments of the device where the venting port 34 would be lower than the surface level of the liquid specimen, such as shown in Figures 5 and 9, a vent extension tube 35 may be provided to move the venting port 34 above the liquid level, although this is optional, since air which is displaced by the advance of fluid into the test wells would bubble thru the fluid in the reservoir. Air in the system vents through the venting manifold 23, and through venting channel 33 into the serum vial.

The intake manifold 15 can be positioned at any point lower than the filling port 32. The positioning of the vent manifold 23 above the surface of fluid in the reservoir assures that all of the test wells will fill and not be cut off by fluid from another test well. The venting manifold 23 of the venting manifold system 21 is positioned higher than the surface level of the fluid in the reservoir when the device is located into operating position. Such positioning of the venting manifold 23 assures that all of the test wells will fill and not be cutoff by fluid from another test well. Flow of the fluid is from the reservoir into the filling manifold system 13, into the test wells 19, out of the test wells 19 and into the venting manifold system 23 and out of the venting manifold system 15 through venting channel 33 and back into the serum vial.

The disposable, self-pipetting, multi-well device of the present invention provides a disposable cartridge for the delivery of small amounts (about 100 microliters) of fluid to a series of wells from one source. Gravity is used to move the fluid without need for the provision of a pressure source or a vacuum source. As shown in Figure 1, when located in operational position, the venting port 34 of the venting manifold system 23 at the end of the venting channel 33 is higher than the inlet at the end of the filling channel 31 which connects with the filling manifold system 13.

As shown in Figures 4, 5 and 6, which are

2. A device in accordance with Claim 1 wherein said docking port is located in an intermediate position between said filling manifold and said venting manifold.

3. A device in accordance with Claim 1 wherein a reservoir containing a fluid specimen is affixed to said docking port.

4. A device in accordance with Claim 3 wherein the fluid specimen has a top level and said venting manifold is located at a position higher than the top level of said fluid specimen when said device is positioned in said operational orientation.

5. A device in accordance with Claim 1 wherein reagents are disposed in said test wells.

6. A device in accordance with Claim 1 wherein predetermined groups of test wells are coupled in sequence by interconnecting passageways.

7. A device in accordance with Claim 6 wherein an auxiliary venting passageway is in fluid communication with at least one of said plurality test wells of one of said groups, said auxiliary passageway being isolated from said venting manifold and said auxiliary passageway leading to a venting point and means for exposing said venting port to ambient pressure or to fluid communication with said venting manifold.

8. A device in accordance with Claim 1 which is folded on a horizontal or vertical axis.

9. A device in accordance with Claim 1 which is formed in a curvilinear shape.

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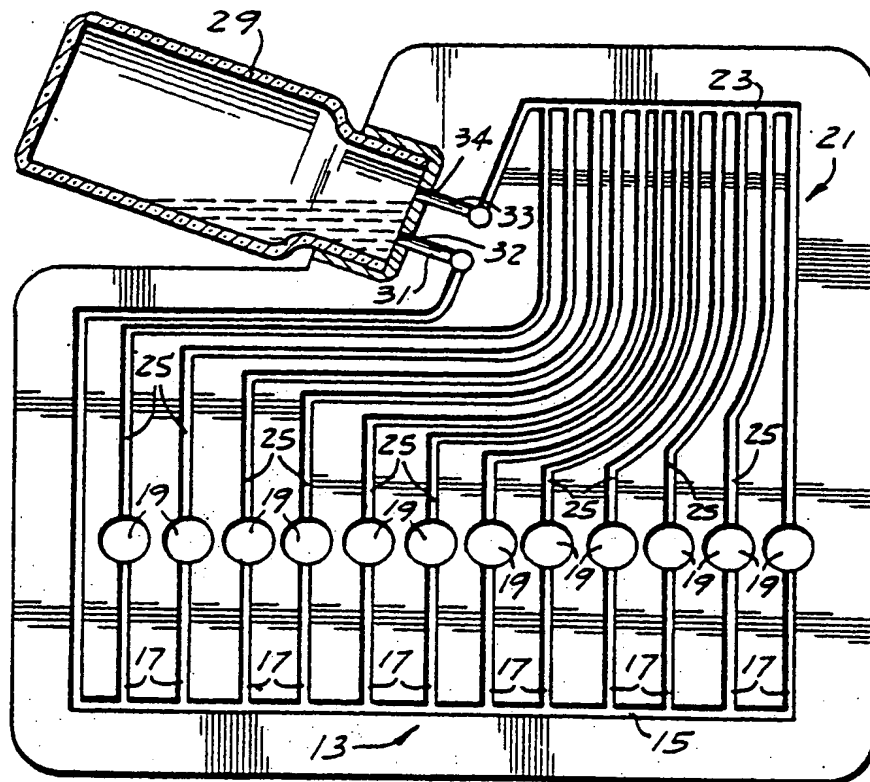


Fig. 4

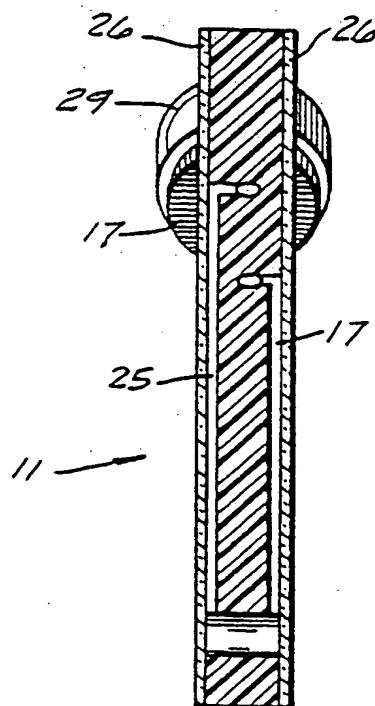


Fig. 3

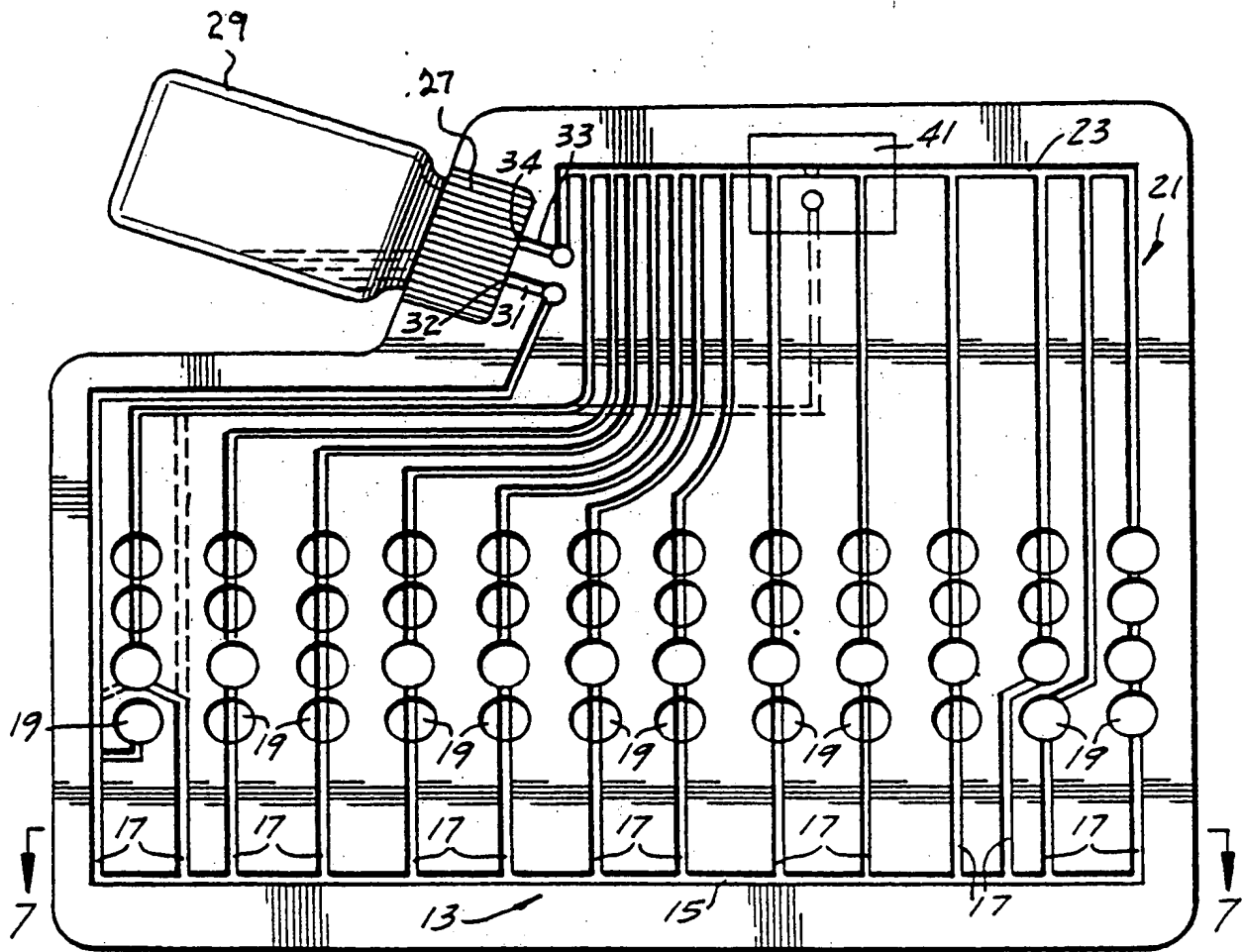


Fig. 6

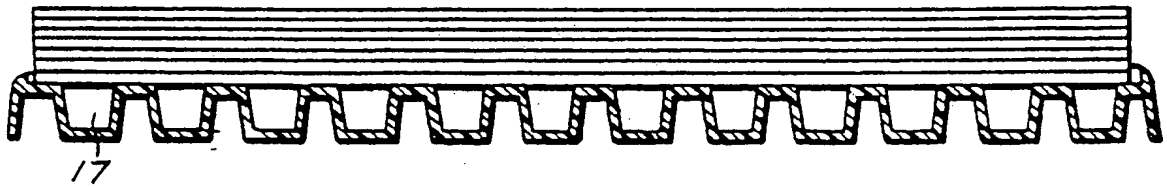


Fig. 7

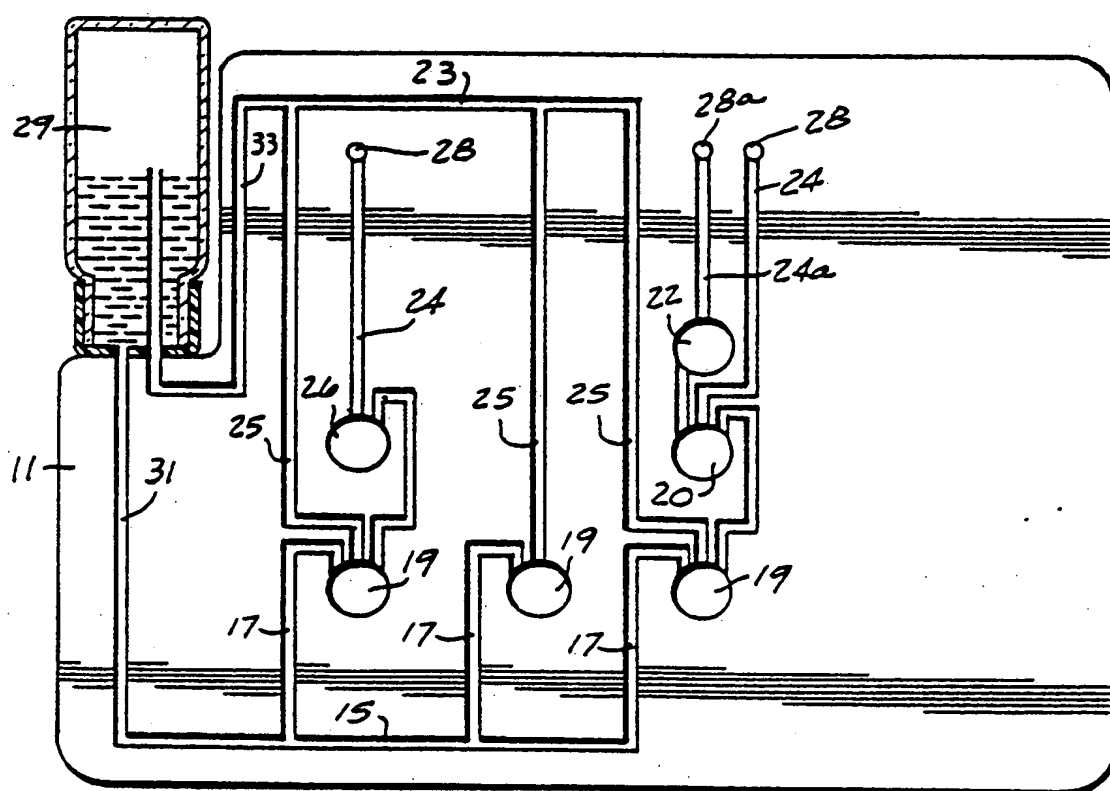


Fig. 9

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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X	US-A-3 957 583 (GIBSON) * Figures 1,4; column 3, line 42 - column 4, line 19; claims 1-3,15 *	1-9	C 12 M 1/32 C 12 M 1/18
A	US-A-4 318 994 (MEYER) * Claims 1,2 *	1	
A	US-A-4 018 652 (LANHAM) * Figures 1,5,6; claims 1,5 *	1-3	
A	US-A-4 330 627 (THOMAS) * Figures 1-3; claims 1,4,5 *	1,5,6	
A	FR-A-1 598 197 (CINQUALBRE) * Abstract; page 5, lines 15-30; figure 1 *	1,5	
A	US-A-4 207 394 (ALDRIDGE) * Claims 1-8 *	1,5	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
			C 12 M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 05-12-1989	Examiner EPAILLARD P.J.H.M.
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	